IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: CAROL CARTER, ET AL.	)	Confirmation No: 6642
	)	
Application No.: 10/666,997	)	Group Art Unit: 1648
	)	
Filed: SEPTEMBER 18, 2003	)	Examiner: L. HUMPHREY

For: TSG101 AS INHIBITOR OF HIV PRODUCTION

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

This Brief is presented in support of the Notice of Appeal, filed August 11, 2009, from the final rejection of Claims 93-94 and 132-134 of the above-captioned application, as set forth in the Final Office Action mailed May 11, 2009.

The requisite fee of $245.00 (application is Small Entity) for filing this Brief is concurrently being paid electronically.

An oral hearing is requested. A separate request for oral hearing with the appropriate fee will be filed within two months of the Examiner's Answer.

A request for extension of time accompanies this filing.

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STATUTES

I. REAL PARTY IN INTEREST

Real parties-in-interest include the Board of Trustees of the Leland Stanford, Junior University and the Research Foundation of the State University of New York the assignees of the application on appeal. Functional Genetics, Inc. of Gaithersburg, Maryland, holds an exclusive license from both assignees in this application.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings that may be related to, directly affect, be directly affected by, or have some bearing on the Board's decision. Appellants submit that the issuance of parent patent U.S. Patent 7,494,767 necessarily demonstrates that the claims on appeal are enabled by the pending application as originally filed.

III. STATUS OF CLAIMS

Claims 93-94 and 132-134 are rejected. The claims pending on appeal are Claims 93-94 and 132-134. A copy of the claims is attached hereto as the Claims Appendix.

1-92. (CANCELLED).

93. (REJECTED) A method of inhibiting human immunodeficiency virus (HIV) particle generation comprising administering to cells suspected of being infected with HIV an amount of a compound which inhibits binding between tumor susceptibility gene (TSG101) protein and HIV Gag polypeptide, wherein said compound is a peptide comprising a PTAP motif.

94. (REJECTED) The method of Claim 93, wherein said peptide administration is effective in reducing the amount of HIV particles generated in said cells by at least two-fold, as compared with the number of particles generated in said cells in the absence of said peptide.

95 – 131 (CANCELLED).

132. (REJECTED) The method of Claim 93, wherein said peptide comprises the amino acid sequence of SEQ ID. No. 4.

133. (REJECTED) The method of Claim 93, wherein said peptide interferes with binding between said TSG101 and said HIV Gag by inhibiting interaction in the p6 region of Gag.

134. (REJECTED) The method of Claim 93, wherein said peptide binds to TSG101, and thereby inhibits binding of HIV Gag to TSG101, in the N-terminal E2-like (UEV) domain of TSG101.

IV. STATUS OF AMENDMENTS

Claims 93 and 94 were originally filed in the current application on September 18, 2003, and amended substantively to remove any recitation in the claims requiring administration to people, or the treatment of Aids, in the amendment of August 26, 2008. Claims 132 – 134 were introduced by amendment on February 7, 2008. No amendments were offered in response to the Final Office action, and no amendments are outstanding as not entered.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Applicants' claims are directed to a method of inhibiting HIV particle generation by cells infected with HIV. **Specification, p. 4, ll. 30 – 33.** This is achieved by administering to the HIV-infected cells peptides which comprise a PTAP motif. **Specification, page 17, lines 7 – 20.** These peptides effectively block interaction between a host protein critical for the replication of the viral invader, TSG101, and a late stage protein of the virus itself, HIV *Gag*. In the absence of such interaction, the virus cannot complete its life cycle, and the release of HIV particles (virions) is blocked. **Specification, page 19, lines 1 – 26.** The importance of inhibiting viral release is self-evident. While the specific infected cell may die (its metabolic cellular machinery is hijacked by the virus) by preventing the infecting virus from replicating, the spread of the viral disease is prevented. This may be important therapeutically, **Specification page 9, lines 6 – 31** and it may allow the identification of specific TSG101 mutations that may render the host resistant to HIV. **Specification, p. 11, lines 14 – 31.**

It is equally important to note what Applicants claims are **not** directed too. They are NOT directed to a method of treating AIDS. They are NOT directed to a method of treating HIV. They do not require administration of an amount effective to do anything other than the claim recitation – inhibiting viral particle release. Inhibiting viral particle release from a cell infected with HIV does not call for inhibition of the virus, destruction of the virus, specificity for the virus, or any of the other myriad factors that the Examiner maintain render these claims insufficiently enabled. The claims were specifically amended not to require such achievements and recitations.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole rejection of all claims on appeal is for lack of enablement, 325 U.S.C. §112, first paragraph. The Examiner asserts that because there Applicants' disclosure lacks teaching about such things as "binding specificity, selectivity and affinity, oral bioavailability, cellular uptake, toxicity, lethal does, and side effects for administering a PTAP-containing peptide into a cell inside a body" the claims are not enabled. Final Office Action of May 11, 2009, page 6. At pages 6–7 of that action, the Examiner points to a number of factors that she maintains give the art "a high level of uncertainty and unpredictability." Page 6. These include "(1) failure to understand the molecular determinants modulating many viral protein and host cell factor interactions; (2) failure of *in vitro* tissue culture studies and animal model to adequately predict clinical efficacy; (3) failure of many compounds to have acceptable pharmacological properties despite initial favorable *in vitro* and *in vivo* activities; and (4) failure of related structural analogs to function in the desired manner". Id.

The Examiner maintains that the best description of the nature of the enablement problem faced by Applicants is set forth in the 1995 publication of Galt and Karn:

> There can be few tasks in biotechnology that are more challenging than designing anti-viral drugs.

Thus, at page 7, the Examiner concludes because the individual of skill in the art, reading the application as originally filed, is "without sufficient guidance to the safety, bioavailability, plasma concentration and antiviral effect, the experimentation left to those sikilled in the art is undue or unreasonable under the circumstances.

In a 15 page discussion of the various obstacles facing those who would devise a treatment for AIDS, the Examiner never once indicates whether the specification is sufficient to

teach one of skill in the art how to inhibit HIV particle formation in a cell infected with HIV by administering to the cell a peptide which inhibits binding between TSG101 and HIV Gag polypeptide. That, however, is Applicants broadest claim.

The Advisory Action is more succinct. The claims, the Examiner maintains, are sufficiently broad to read on being administered to "a human patient's cell." If the Examiner is referring to a human patient with cells infected with HIV that much is true. The Examiner goes on to say more that is simply incorrect:

> Given its broadest interpretation, [the claims] reads on human patients' cell hence therapeutic treatment. Advisory Action of July28, 2009, ¶ 11.

The Examiner is in error. Whether administered to cells *in vitro* or *in vivo*, whether administered to human cells, mouse cells adapted to host HIV, or simian cells similarly adapted, the claims call for one thing and one thing only – an inhibition in viral propagation. As discussed below, the rejection, as applied to the actual claims presented, is not reasonable.

VII. ARGUMENT

As discussed below, the claims are being rejected NOT because there is inadequate disclosure for what is claimed. The United States Patent and Trademark Office itself has, on more than one occasion, in more than one way, conceded that in fact what is claimed is enablingly disclosed. The sole rejection of all claims pending is based on a rejection of what is NOT claimed.

A. The Claims Do Not Stand or Fall Together.

Specifically, Claim 132, which recites a specific peptide for administration, and Claim 134, which recites that the peptide binds to a specific site (epitope) may be independently patentable. These two claims are discussed separately, below.

B. It is the Claimed Invention that Must Be Enabled

Respectfully, the rejection appealed from loses site of the fact that it is only that which is claimed which is subject to scrutiny for enablement. While it would seem axiomatic, it is not infrequently the case that when a basis for rejecting a claim is explored, the arguments advanced in support of that rejection are not based on the claim itself. This is embodied in the decision of the Federal Circuit in *Sitrick v. Dreamworks, LLC* 516 F.3d 993, 999 (Fed. Cir. 2008).

> "The ' enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation.' " *Sitrick v. Dreamworks, LLC,* 516 F.3d 993, 999 (Fed.Cir.2008) (quoting *AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1238-39 (Fed.Cir.2003)). (Emphasis supplied).

This is not a new element of the law, however. The Federal Circuit has made this a basis for claim review since its founding. Our caselaw is replete with the admonition that it is the claims, and the claims alone, not the specification, that measures what the invention is, and identifies the

metes and bounds of what must be enabled. *Environmental Designs, Ltd. v. Union Oil Co. of California*, 218 USPQ 865, 870 (Fed. Cir. 1983). See also, *Raytheon Co. v, Roper Corp.*, 220 USPQ 592, 598 (Fed. Cir. 1983) (*Reversing a rejection based on a failure of the specification to enable preventing "autoignition" when the claims only called for "preventing explosions by restircitng the the air path to limit the excess of air" below the level productive of explosions.*)

This Board has a similar history. The decision in *Ex parte Dill*, 214 USPQ 389, 391 (BPAI 1981) is instructive. The claims on appeal were directed to a method of making a semiconductor device, specifically, an insulated gate field effect transistor. One aspect of the claims was the formation of a field oxide. The claims were rejected for lack of disclosure, as are the claims herein, for failure to disclose "the final thickness of the silicon dioxide forming the field." P. 389. The Board did not sustain this rejection:

> Here, the claims at bar do not define a field oxide. Nor do the claims describe process for making an integrated circuit or an array where a field oxide might be needed. Hence, the appellant need not disclose the final thickness of a field oxide. Accordingly, we will not sustain this ground of rejection. 214 USPQ 391.

It is worth noting that in fact the effects of the field oxide and its importance in the operate of the gated transistor are discussed at some length in the specification. See, U.S. Patent 3,544,399 – the disclosure relied on, Column 1, lines 27–60.

Herein, Applicants respectfully submit the Examiner has based her rejection not on the claimed invention, but rather, on the discussion in the specification of the potential for therapeutic application of the invention. While it is Applicants hope that therapy for HIV infection may be made a reality through, in part, their efforts, *that is not what they have claimed.* Broad Claim 93 was specifically amended to avoid claiming treatment or therapy. Fundamentally, and without seeking to be graphic or cruel, it makes no difference to the claimed

invention if the cell to which the peptide is administered is a cell of a human being, and if it is, if that human being suffers from AIDS or not, and if it does, if the AIDS sufferer dies, survives or improves. That is not an aspect of Applicants claims. Inhibition of particle formation is all that is required. This has an importance in its own right. In point of fact, the Office has recognized the difference. In the Restriction Requirement issued October 19, 2006, the Office drew a line of patentable distinction between inhibiting viral budding from a host cell, and treating or preventing AIDS. See, Page 3. Having already noted that Applicants claims are distinct from claims directed to AIDS prevention, the Office should not now reject the pending claims for failure to disclose what the Office has said is a patentably distinct invention.

Thus, the fundamental flaw in the rejection is not the Examiner's discussion of the many problems involved in finding a treatment for AIDS. This is indeed a difficult task. But it is NOT Applicants' invention. In Applicants' invention, the infected cell is not saved, is not treated. Thus, the Examiners "hence therapeutic treatment" is an invalid conclusion. What Applicants seek to block is viral propagation beyond the infected cell, ot inhibit the virus particle generation by an infected cell. Nothing is offered about a treatment or cure, not of the infected cell. The infected cell remains infected. If there are many cells so infected, in a human, the human is likely to remain infected. This is not offered as a cure, and certainly not claimed as one. The concerns of the Examiner with respect to "safety, bioavailability, plasma concentration and antiviral effect" and the noted problems in the field in addressing "(1) failure to understand the molecular determinants modulating many viral protein and host cell factor interactions; (2) failure of *in vitro* tissue culture studies and animal model to adequately predict clinical efficacy; (3) failure of many compounds to have acceptable pharmacological properties despite initial favorable *in vitro* and *in vivo* activities; and (4) failure of related structural analogs to function in

the desired manner" may be relevant to a claim that purports to treat an HIV infected individual, or cure AIDS. Applicants claim neither. As discussed below, what Applicant claims is acknowledged to be enabled.

C. **The Recited Steps of the Claims Are Enabled**

Applicants' claims are drawn to a method. When measuring enablement, it is proper to consider the broadest reasonable construction of those claims, bearing in mind that an Applicant for patent need to disclose only a single method for practicing those claims. In particular, the level of disclosure varies according to the specific limitations of the claims – what do the claims require. *Durel Corp v. Osram Sylvania, Inc.,* 256 F.3d 1298, 1306-07, 59 USPQ2d 1238, 1243 - 44 (Fed. Cir. 2001).

The claims – in their very broadest rendition, require only that a peptide be administered to cells infected with HIV. There is nothing difficult about that – this has been done for years and the specification is replete with examples of this. The claims, in their very broadest rendition, further require that the administered peptide comprise a PTAP motif. There is nothing difficult or not enabled about this....those of skill in the art know HOW to prepare peptides with a PTAP sequence or motif, and even if they did not, the specification contains examples of the same, including SEQ ID Nos. 3 and 4. This is clearly enabled.

The claims, in their broadest rendition, further require that the PTAP comprising peptide be administered to the cells in an amount which inhibits binding between tumor susceptibility gene protein (TSG101) and HIV Gag polypeptide. And this of course is what the case is all about, the very long specification demonstrating by specific example, including assays and results, that peptides of the type recited do indeed inhibit binding between TSG101 protein and

HIV Gag polypeptide. Because this binding event is a prerequisite for HIV particle generation, the administration of these particles inhibits that generation. Here is what the Examiner and the Office had to say about whether the specification enables one of skill in the art to identify these PTAP comprising peptides that interfere with binding between TSG101 and HIV Gag protein:

> The instant specification discloses…an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation step in the virus lift cycle.

See, Office Action of November 25, 2008 at page 8 and Office Action of May 11, 2009, page 10. Applicants agree with the Examiner that the specification does in fact enable one to find the class of peptides recited in the claims!!!

Thus, Applicants respectfully submit that all aspects of the **claimed** invention are enabled. One can see this as follows:

Claim 93 recitations	**Record Evidence**
Administering to cells suspected of being infected with HIV an amount of a compound	This has been done for years, but the specification specifically teaches administration of this compound, and amounts to be administered. Pages 17 – 18, pages 31, 34, 41.
The compound is a peptide comprising a PTAP motif	Even a freshman chemistry student can construct and recognize a peptide which comprises a PTAP motif. But examples are given in SEQ ID Nos 3 and 4
The peptide comprising the PTAP motif inhibits binding between TSG101 protein and HIV Gag polypeptide and thereby inhibits HIV particle generation	The instant specification discloses…an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation

	step in the virus lift cycle. Office Actions of November 25, 2008 and May 11, 2009.

The key to enabling this invention is the disclosure of a method which will allow one of skill in the art to identify the essential peptide – one that blocks or interferences with or otherwise inhibits binding between HIV Gag and TSG101. This is Applicants discovery, that such peptides do exist, can be identified and prepared, and used to inhibit viral particle generation. The remaining steps are facilitating only, and do not require a particular level of sophistication or skill in the art. It is anomalous that the Office would agree, expressly, that the disclosure is enabling for this recitation of the claims, but nonetheless not enabled for the rest, which calls for nothing more than administration of the peptides to a cell.

That which is not claimed need not be enabled. The Examiner has seized on the "ultimate embodiment" of the disclosure. In the very best of worlds, the recited method will provide a treatment for some individuals to address or prevent AIDS. But that is the ultimate commercial embodiment, not what Applicants are claiming. Our case law warns against requiring an inventor with modest claims to disclose this "ultimate embodiment." In *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F. 3d 1333, 1338–39, the Federal Circuit noted that, absent a claim limitation drawn to such an embodiment, one need not enable it.

> Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect. Title 35 requires only that the inventor enable one of skill in the art to make and use the full scope of the claimed invention. Thus, when an invention claims a general system to improve the cleaning process for semiconductor wafers, the disclosure enables that

invention by showing improvements in the overall system. *See, e.g., Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed.Cir.1991).

Here, the claims call only for inhibiting HIV particle formation. Not treating AIDS, not preventing HIV, not even curing the cell to which they are administered. These claims should not be rejected for failure to disclose that which they do not recite.

Respectfully, this rejection should not be sustained.

D. **Issuance of U.S. Patent 7,494,767 Supports Enablement**

On February 24, 2009, the USPTO caused to issue U.S. Patent 7,494,767. This patent is the parent of the case on appeal. It has a disclosure identical to that of the Application on appeal, It names the same inventors as those named in the case on appeal. The patent was considered in part by the same Examiner as the Examiner responsible for this case on appeal, Dr. Humphrey. That patent claims, in one of its broadest expressions:

1. A method for identifying a peptide or fragment derived from a mammalian tumor susceptibility gene 101 (Tsg101) protein, wherein the peptide or fragment is effective in reducing HIV particle production, said method comprising: (a) introducing an expression construct into a mammalian cell or cells, wherein the expression construct comprises a portion of a mammalian tsg101 gene; (b) introducing one or more expression constructs into the mammalian cell or cells, wherein the one or more expression constructs comprise the HIV gag, pol, and rev gene sequences; (c) incubating the transfected mammalian cell or cells in a suitable media for a sufficient time and at a temperature of about 37.degree. C. to obtain a mammalian cell culture comprising mammalian cells which express a mammalian Tsg101 peptide or fragment and HIV Gag, Pol and Rev proteins; (d) measuring the level of particle-associated p24 in the mammalian cell culture; and (e) correlating a reduced level of particle-associated p24, when compared to a control mammalian cell culture which has not been transfected with the expression construct comprising a portion of a mammalian tsg101 gene, with the identification of a peptide or fragment effective in reducing HIV particle production.

Thus, the claims recite a method which results in the reduction of the level of particle associated p-24 (HIV virions particles) by providing (administering) to the cell a peptide effective in

reducing HIV particle production. It is worth noting that narrower claims of this patent specify that the peptide is one which binds to the PTAP motif of an HIV Gag protein. Claim 24.

U.S. Patent 7,494,767, with a disclosure identical to that of the application on appeal, is presumed enabling. *Amgen Inc. v. Hoechst Marion Roussel* Inc., 65 USPQ2d 1385, 1416 (Fed. Cir. 2003), *Sanofi-Synthelabo v. Apotex Inc.,* 89 USPQ2d 1370, 1376 (Fed. Cir. 2008). As previously noted by Applicants, if the same disclosure is enabling for the method of identifying and using these peptides, then the necessary conclusion is that the pending disclosure must be as well.

The Examiner does not disagree, but says only:

> U.S. Patent 7,494,767 is not germane to the rejection at issue because each case is evaluated on its own merits. Office Action of May 11, 2009, p. 12.

> Applicants citation of US Patent 7,494,767 is not germane to the instant application and rejection at issue because the claims are entirely different. Advisory Action of July 28, 2009, ¶11.

Respectfully, the Examiner is wrong. The case law of the Federal Circuit establishes that the disclosure provided in the above application is presumed to be enabling for the peptides in question, independent of its "own merits." While it is true that in fact the claims are different, the claims on appeal herein are nothing more than claims directed to a method of using the peptides identified by the claims of the issued patent. The claims of U.S. Patent 7,494,767 are presumed enabling for the purposes of practicing and using the claims presented. To use the particles identified, one needs to administer them to the cells, as taught. That, and nothing else, is what is claimed.

The law of the reviewing Court is not that once a patent issues its presumption of enablement is relevant ONLY to the claims issued patent. The Court found the presumption to

be compelling when considering what the issued patent taught those of skill in the art with respect to the claims of another patent with, in the words of the Advisory Action "claims (which) are entirely different." The Court observed in *Amgen*:

> We do not rely on §282 as the source of a presumption. Instead, relying on our precedent, we hold a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled. 65 USPQ2d at 1416.

While in fact one can rest on the enablement of the subject matter claimed in the '767 patent as sufficient to support enablement herein, the presumption is not so limited. While it is true that the '767 patent is not prior art against the pending case for all purposes, that should not impact the presumption to which it is entitled. It is true that the Court found in *Apotex* that the existence of the presumption did not preclude an investigation into whether one of skill in the art could successfully practice the recited steps – the Examiner does not identify any recited step as difficult or not enabled. Rather, the Examiner insists Applicants have not enabled the prevention of AIDS. One can argue that forward and back but it is not germane to the issue before this Board, as it is not claimed. Confining the issues raised to the claims presented, the sole rejection for lack of enablement should not be sustained.

E. **All the Claims Do not Stand or Fall Together**

It is not clear whether the Examiner agrees with her earlier observation that the disclosure allows one to identify the peptides necessary to the practice of the invention. At parts of the outstanding Final Office Action the Examiner is critical of the limited number of examples recited in the specification. See, Office Action of May 11, 2009, page 4. To the extent this is carried forward on Appeal, Applicants note that Claim 132 is limited to the specific peptide of the Examples (SEQ ID 4) shown to be effective. While it is unclear why those of skill in the art

could not construct other peptides given the disclosed assay and examples, this criticism of the enabling disclosure is clearly not applicable to Claim 132.

By the same token, although Claim 134 is slightly broader than Claim 132, it nonetheless specifies that the peptide binds to TSG101, and thereby inhibits HIV Gag binding, in the N-terminal E2-like (UEV) domain of TSG101. This is a well studied and well characterized domain of this human protein. It would not be a challenge to those of skill in the art to design a PTAP motif-comprising peptide that binds to TSG101 in this particular domain.

Clearly, with respect to enablement, while all claims are enabled, Claims 132 and 134 are closely focused on specific families of peptides that the specification teaches those of skill in the art to make.

The rejection for lack of enablement as to these claims should not be sustained.

VIII. SUMMARY

On the basis of the foregoing, Applicant respectfully submits that Claims 93-94 and 132-134 are enabled by the disclosure of the Application on appeal as originally filed, and respectfully request the rejection outstanding be reversed and returned.

Please charge any additional fees due or credit any overage to Deposit Account 50-0548.

Date: November 19, 2009

Respectfully submitted,

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IX. CLAIMS APPENDIX

1-92. (CANCELLED).

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132. (PREVIOUSLY PRESENTED) The method of Claim 93, wherein said peptide comprises the amino acid sequence of SEQ ID. No. 4.

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134. (PREVIOUSLY PRESENTED) The method of Claim 93, wherein said peptide binds to TSG101, and thereby inhibits binding of HIV Gag to TSG101, in the N-terminal E2-like (UEV) domain of TSG101.

X. EVIDENCE APPENDIX

The following is a list of references entered by the Examiner and/or relied upon by Appellant in this appeal, along with a statement setting forth where in the record that evidence was entered by the Examiner and/or the Appellant. Copies of each piece of evidence are provided herewith.

REFERENCE	LOCATION IN THE RECORD
U.S. Patent 7,494,767	Amendment of February 25, 2009, page 23
Admission that an assay for identifying all PTAP-containing peptides that are effective at inhibiting the binding between Tsg101 and the HIV Gag protein and thereby blocking the HIV particle generation step in the virus lift cycle.	Office Action of November 25, 2008, pages 5 – 6.

XI. RELATED PROCEEDINGS APPENDIX

NONE.